OCT 1 0 2008

K082646

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact:

Monika Campbell
Senior Regulatory Affairs Specialist
Telephone +1-310-348-4293
Fax +1-310-410-5519
E-mail: mcampbell@ksea.com

Device Identification:

Common Name:
Karl Storz Pediatric Flex-X^{2TM}

Trade Name:
Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and Accessories

Indication: The Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and Accessories are intended used for by a physican in thevisual examination and treatment of a variety of urological endoscopic procedures for pediatric patients.

Device Description: The Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and Accessories includes a flexible endoscope and accessory items designed for treatment of urological endoscopic procedures. The Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope is a Class II device under 21CFR876.1500, Endoscope and accessories.

Substantial Equivalence: The Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope is substantially equivalent to the predicate device since the basic features and intended uses

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are the same. The minor differences between the Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of these devices.

Signature:

Monika Campbell
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2008

Ms. Monika Campbell
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
CULVER CITY CA 90230

Re: K082046
Trade/Device Name: Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Dated: September 30, 2008
Received: October 1, 2008

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K082046

Device Name: Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and Accessories

Indications for Use: The Karl Storz Pediatric Flexible Cysto-Urethro-Fiberscope and accessories are intended used for by a physican in thevisual examination and treatment of a variety of urological endoscopic procedures for pediatric patients.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082046